

BAKER BOTTS LLP.Attorney Docket No.: A32011-A-PCT-USA (072448.0313)
PATENT**REMARKS**

This paper is being filed in response to the final Office Action dated October 16, 2003, which issued within two months of the filing of the instant reply.

Claims 1-23 were pending. Claims 10-23, which were withdrawn from further consideration pursuant to 37 C.F.R. 1.142(b) for being drawn to nonelected inventions, are canceled herein, without prejudice to Applicants' right to prosecute the canceled subject matter in other applications, and subject to Applicants' preservation of rights pursuant to the traversal of the Restriction Requirement dated January 28, 2003.

Claims 1 and 5 are amended herein and contain no new matter. Support for the amendments can be found in the specification, claims and drawings as originally filed. Accordingly, Claims 1-9 remain pending.

Claims 1 and 2 stand rejected under 35 U.S.C. § 102(b) as allegedly being unpatentable over Kim et al., 1995, *Biotechnol. Prog.* 11(4):465-467 ("Kim") and U.S. Patent No. 5,552,086 to Siiman et al. ("Siiman").

Claims 5-9 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Kim and Siiman. Alternatively, Claims 5-9 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Kim and Siiman.

Claims 1-4 are also rejected under 35 U.S.C. § 103(a) as allegedly obvious over Kim in view of U.S. Patent No. 5,232,829 to Longiaru et al. ("Longiaru").

Further, Claims 1-4 are rejected under 35 U.S.C. § 103(a) as allegedly obvious over Siiman in view of Longiaru.

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PATENT**Rejections Under 35 U.S.C. § 102(b)**

The rejection of claim 1 under 35 U.S.C. § 102(b) as allegedly anticipated by Kim has been maintained. The October 16, 2003 Office Action alleges that the phrase "bioassay plate" has no patentable weight in the original claims because the phrase appears in the preamble. As a result, Applicants' explanation in its response filed on August 1, 2003 that the chromatography support of Kim is significantly different from a clear bioassay plate and assertion that Kim does not teach high density binding of active biotin-labeled molecules were discounted. The Office Action also states that the claimed invention comprises immobilized silver ions and a support, both of which are allegedly taught by Kim. For similar reasons, Claims 5-9 remain rejected as allegedly anticipated by, or in the alternative, as allegedly obvious over Kim.

Applicants disagree with the assertion that presentation of the phrase "bioassay plate" in the preamble precludes any patentable weight. Nevertheless, Applicants have rewritten Claim 1 and Claim 5 to recite the term "plate" in the body of the claim. As such, Applicants respectfully submit that the amended claims clearly define the invention as a bioassay plate having silver ions immobilized thereon, and thus cannot be anticipated by the cited art.

To anticipate a claim, a reference must teach every element of the claim. *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."); *see also* M.P.E.P. § 2131. Kim does not anticipate the claimed invention because Kim teaches a chromatography support (*i.e.* Bio-Gel P-2 polyacrylamide gel) and not a bioassay plate. The two supports are not at all

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alike, which is evidenced by the requirements for proper functioning of a bioassay plate that differ from a chromatography resin in many ways. For example, the successful binding of a high concentration of biotin-labeled molecules that remain bioactive while on the surface of a bioassay plate is not taught or suggested by Kim. Also, procedures to avoid undesired binding of non-targeted molecules in the bioassay is not taught or suggested by Kim's work on chromatographic supports. Most importantly, the immobilization of silver ions on the bioassay plate of the instant invention does not critically change the optical properties of the plate (*i.e.* the plate remains substantially transparent). In direct contrast, the chromatographic resin of Kim darkens in color, which indeed teaches away from maintaining optical properties that are instrumental to ELISA and other light-based detection methods widely used in plate-format bioassays. By simple virtue that a chromatographic resin is not a bioassay plate, Kim fails to teach every element of the claim, and consequently cannot anticipate the claimed invention.

Siiman similarly does not anticipate the claimed invention. Siiman discloses aminodextran compounds deposited on the surface of a colloidal size substrate to coordinate to and reduce metal salts or complexes to a metallic or metal(O) species which uniformly coat the surface of the aminodextran-coated colloidal substrate. Though Siiman provides that "[i]n the biotechnical and immunological examples given, solid, non-porous polymeric substrates [*e.g.* polystyrene] are preferred" (Col. 7, lines 31-34), the aminodextran (not the silver ion) is directly adsorbed to the surface of the substrate. Because aminodextran, and not silver metal or silver oxide, is used as the surface species, Siiman does not teach every element of Claims 1 and 2, and thus cannot anticipate the presently claimed invention.

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Accordingly, Applicants respectfully submit that the rejections of the claims under 35 U.S.C. § 102(b) should be withdrawn.

Rejections Under 35 U.S.C. § 103(a)

The rejections of Claims 1-4 under 35 U.S.C. § 103(a) as allegedly obvious over Kim in view of Longiaru, or over Siiman in view of Longiaru, have been maintained. The October 16, 2003 Office Action contends that one of ordinary skill in the art would have had an expectation of success to make the asserted combination because Kim, Siiman, and Longiaru disclose a polymeric support.

Applicants disagree with the assertion that one of ordinary skill in the art would have had an expectation of success to make the asserted combinations. In response to the Office Action, however, Applicants have rewritten Claim 1 and Claim 5 to recite the phrase "wherein said plate is substantially transparent" such that the amended claims cannot be obvious in view of the cited art. The standard for obviousness requires that the cited art teach or suggest each and every limitation of the claims. Further, the Court of Appeals for the Federal Circuit has held that there can be no suggestion or motivation to modify a reference if doing so would render the prior art device inoperative for its intended purpose. *See e.g. In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984).

Without describing particulars, the Office Action asserts that "[o]ne of ordinary skill in the art would have expectation for success to combine the teaching of Kim et al. and Longiaru et al. because a plate format would provide the advantages of a quicker assay time and a less labor intensive assay format" (Office Action at page 11). Applicants point out, however, that the resin of Kim is – at a minimum – opaque. Because of this property, the proposed

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application of the Kim resin to the Longiaru plates would render the Longiaru plates unfit for their intended purpose. Reciprocally, the separation of amino acids sought to be achieved by Kim could not reasonably be accomplished by applying the Kim resin to a plate. Therefore, a suggestion or motivation to combine Kim and Longiaru as proposed is lacking. Indeed, the references teach away from any such combination.

With respect to the rejection over Siiman in view of Longiaru, the Office Action again asserts, without providing specifics, that "[o]ne of ordinary skill in the art would have been motivated to include a support in a plate format in the device of Kim et al. [*sic*, Siiman et al.] for the advantage of a quicker assay time and a less labor intensive assay format" (Office Action at page 12). However, once again the asserted combination would render both the particles of Siiman and the plates of Longiaru inoperative. Since the metal-coated colloidal particles of Siiman are used in flow cytometry methods, which take advantage of the particle's light-scattering properties, the application of the particles of Siiman to the plates of Longiaru would render the Siiman particles unfit for their intended purpose, *i.e.* immobilized particles cannot be used in flow cytometry applications.

Reciprocally, incorporating the light-scattering particles of Siiman into the plates of Longiaru would render the plates unsuitable for hybridization capture of PCR-amplified DNA for at least three reasons. First, given the high affinity of biotin for silver, introducing silver to the plates of Longiaru would lead to unacceptably high levels of non-specific binding of PCR-amplified DNA labeled with biotin. In fact, it would be readily apparent to one of ordinary skill in the art that it would be nearly impossible to detect specific binding interactions under such conditions. Second, the light-scattering property of the particles of Siiman would interfere with

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the colorimetric detection methods taught by Longiaru. Third, passive binding of the Longiaru capture probe may be reduced or blocked if the plates are first coated with the particles of Siiman. Consequently, no suggestion or motivation to combine these references can be inferred. Indeed, the references teach away from any such combination.

Accordingly, Applicants respectfully submit that the rejections of the claims under 35 U.S.C. § 103(a) should be withdrawn.

Conclusion

Applicants respectfully request reconsideration of the outstanding rejections, and entry of the above amendments and remarks into the file history of the above-identified application. Applicants believe that the above amendments and remarks place the claims in condition for allowance, and accordingly, respectfully request withdrawal of the outstanding rejections. An early allowance is earnestly sought.

Respectfully submitted,

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